

for entry in the application.

The objection to the Declaration is respectfully traversed. It is respectfully submitted that each applicant did in fact sign the declaration with both a family and given name. Additionally, the Declaration identifies the application by reference to its International application number and filing date, thereby sufficiently identifying the application. Withdrawal of the objection to the Declaration is respectfully requested.

The rejection of the claims under 35 U.S.C. 112, second paragraph, is respectfully traversed. Claims 4 and 10 have been canceled, claims 7 and 13 have been canceled and their limitations inserted into claim 6 and 12, and claim 1 has been amended clarifying the conductive layer as requested. Also, claim 2 has been clarified as requested. Therefore, withdrawal of this rejection of the claims is respectfully requested.

The following rejections of claims are each respectfully traversed:

- (1) the rejection of claims 1, 2, 4, 8, 10, and 14 under 35 U.S.C. 102 or, alternatively, under 35 U.S.C. 103 over Carter et al (US 5,628,890);
- (2) the rejection of claims 3 and 9 under 35 U.S.C. 103 over Carter et al. in view of Hill et al (US 5,820,551);
- (3) the rejection of claims 5 and 11 under 35 U.S.C. 103 over Carter et al. in view of Durst et al. (US 6,248,596); and
- (4) the rejection of claims 6, 7, 12 and 13 under 35 U.S.C. 103 over Carter et al. in view of Maley et al. (US 5,770,028) and Johnson et al. (US 5,429,735).

Each of these rejections is based on the disclosure contained in the principal reference Carter et al. It is respectfully submitted that the following discussed deficiencies in the disclosure of Carter et al., which are not cured by the disclosure in any of the secondary references, renders each of these rejections erroneous and requires their withdrawal.

The device and method of the instant claims are both novel and unobvious

over the disclosure in Carter et al., alone or with any of the secondary references. The device in Carter et al. is a device having an aperture within the second non-conductive layer. Figure 1 of Carter et al. clearly shows the location of aperture 12 within the electrically insulating ink 11. By contrast, as shown in Figure 1a of the instant application, the sample application area 9 is at one edge of the novel device, as disclosed in the specification at page 2, line 24-26 and page 7, lines 29-36. Thus the claims are novel over Carter et al.

Additionally, the claimed subject matter is unobvious over the reference disclosures. Having the sample application area at one edge of the device is a significant and unobvious aspect of the invention that is neither disclosed or suggested by any of the reference disclosures. This feature allows easier collection of blood from a patient in contrast to the prior art devices, e.g. of Carter et al. In attempting to use the device of Carter et al, the aperture cannot be seen by the user (who must hold the device in his hand and extend it toward the patient) making the sample collection step difficult. However, to use the device of the present invention, one need merely contact the edge of the claimed device with the collection site. For the convenience of the USPTO Examiner, attached to this response is a sketch illustrating the difference between the claimed device and that of Carter et al. This aspect is not rendered obvious by any of the prior art. Therefore, the USPTO is respectfully requested to reconsider and withdraw the afore-mentioned 35 U.S.C. 103 rejections of the claims.

Newly presented claim 15 is also patentable over the cited references for at least the same reasons.

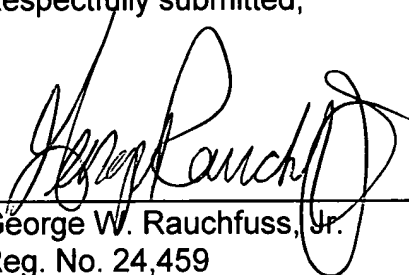
For the further information of the USPTO, it is to be noted that the Carter et al reference was cited in the Written Opinion in the PCT application and, in the International Preliminary Examination Report (IPER), both novelty and inventive step were found to exist over this reference disclosure. A copy of that IPER was previously submitted to the USPTO.

It is respectfully submitted that the foregoing is a full and complete response to the Office Action and that all the claims are allowable for at least the reasons

indicated. An early indication of their allowability by issuance of a Notice of Allowance is earnestly solicited.

Respectfully submitted,

By:



George W. Rauchfuss, Jr.
Reg. No. 24,459
Attorney for Applicant

Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
One Landmark Square, Tenth Floor
Stamford, CT 06901-2682
Tel: (203) 327-4500
Fax: (203) 327-6401

Date: December 10, 2001

MARKED-UP COPY OF AMENDED CLAIMS

1. (Amended) A device for use in the electrochemical analysis of an analyte in a liquid sample, which comprises:

a non-conducting substrate;

a discontinuous conductive layer deposited on adjacent first and second portions, respectively, of the non-conducting substrate [in two parts] and defining a non-conducting gap [therebetween] between the first and second portions;

an analyte-specific reagent coated on the conductive layer[, on one side of the gap] on the first portion;

a reference electrode on the conductive layer [,on the other side of the gap] on the second portion;

a spacer layer deposited over the conductive layer;

a monofilament mesh coated with a surfactant or chaotropic agent, the mesh being laid over the analyte-specific reagent, the reference electrode and the spacer layer; and

a second non-conductive layer, adhered to the mesh layer, but not co-extensive therewith, thereby providing a sample application area at one edge of the mesh.

2. (Amended) A device according to claim 1, wherein the reagent does not contain [is free of] filler having both hydrophobic and hydrophilic surface regions.

6.(Amended) A device according to claim 1, wherein the first conductive layer comprises graphite particles, carbon particles and a polymer binder, wherein the graphite particles have an average particle size of 1-20 μ m and a surface area of 1-50m²/g, and the carbon particles have an average size of 5-70 nm and a surface area of less than 150m²/g.

12.(Amended) A device according to claim 2, wherein the first conductive layer comprises graphite particles, carbon particles and a polymer binder, wherein the graphite particles have an average particle size of 1-20 μ m and a surface area of 1-50m²/g, and the carbon particles have an average size of 5-70 nm and a surface area of less than 150m²/g.